

Remarks

Reconsideration of this application in view of the above amendments and following remarks is respectfully requested.

Claims 15-153 are now pending. Claims 1-14 have been canceled. Claims 24-153 are new. Claims 15-23 have been withdrawn from consideration by the Examiner. In that regard, Applicants note that the Examiner has previously indicated that, should compound and composition claims 1-14 (now claims 24-153) be found allowable, method claims 15-23 would be rejoined for further prosecution.

As an initial matter, Applicants have added new claims 24-153 to more specifically recite certain embodiments of this invention. The subject matter of these claims finds specific support throughout the specification and does not constitute the addition of new matter.

Claim 1 (now claim 24) stands rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claim 1 of U.S. Patent No. 6,197,750, and stands provisionally rejected under the same doctrine over claim 30 of U.S. Application No. 09/745,204, which has now issued as U.S. Patent No. 6,544,951. (For the Examiner's convenience, copies of both of these patents are enclosed.) To obviate these grounds of rejection, Applicants submit herewith appropriate and timely filed Terminal Disclaimers.

The Examiner notes that this application contains sequences disclosures encompassed by the definitions for amino acid sequences set forth in 37 C.F.R. §1.821. Accordingly, please find enclosed electronic and paper copies of the Sequence Listing which include no new material that goes beyond the disclosure of the above-identified application as originally filed. Applicants respectfully submit that the above-identified application is now in compliance with 37 C.F.R. §§ 1.821-1.825 and WIPO Standard 25.

The specification stands objected to for lacking Table 1 and Table 2. For the Examiner's information, the information contained in such tables may be found in the parent application, now issued as U.S. Patent No. 6,197,750 (which application was incorporated by reference in its entirety upon filing this application – *see* page 1, lines 5-9). However, to avoid confusion in the present application, Applicants have omitted reference to "Table 1" at page 43, line 11, and have renumbered Tables 3-17 as Tables 1-15, respectively.

Claims 1-14 (now claims 24-153) stand rejected under §112, first paragraph, for lack of enablement for the reasons set forth in the Office Action at pages 4-5. To overcome this ground of rejection, the Examiner suggests the following:

that (a) applicants provide *in vitro* data which demonstrates that the compounds can inhibit proteases in accordance with the assertions in the specification, and that the term “pharmaceutical” be deleted from claim 14. (See 12/20/02 Office Action, page 5, last paragraph)

As an initial matter, Applicants wish to direct the Examiner’s attention to Table 1 and Table 2 appearing at columns 27, 28 and 29 of U.S. Patent No. 6,197,750, which, as noted above, has been incorporated by reference in its entirety, and which demonstrates that compounds of this invention have the activity asserted.

In addition to the data incorporated by reference from U.S. Patent No. 6,197,750, Applicants also submit herewith the Declaration of Dr. Alfred P. Spada. This Declaration provides further activity data for embodiments wherein R<sup>1</sup> is other than hydrogen (in that regard, the Examiner should note that the data from Tables 1 and 2 of U.S. Patent No. 6,197,750 are embodiments wherein R<sup>1</sup> is hydrogen). More specifically, the Declaration at ¶4 discloses activity for four (4) representative compounds where R<sup>1</sup> is other than hydrogen (*i.e.*, Compound A), or where R<sup>1</sup> and R<sup>1</sup> taken together form a heterocycle (*i.e.*, Compound B) or a substituted heterocycle (*i.e.*, Compounds C and D).

Lastly, the Examiner states that should Applicants provide the *in vitro* data as requested (which Applicants have now done), the Examiner questions whether one can extrapolate such data to support treatment of the claimed indications. To that end, the Examiner suggests that Applicants delete the word “pharmaceutical” from composition claim 14 (now claim 153). While such an amendment would actually result in a broadening of that claim, Applicants wish to retain this term and have provided *in vivo* data to support the same. More specifically, the attached Declaration of Dr. Alfred P. Spada at ¶6 through ¶10 presents *in vivo* data for a representative compound of this invention (*i.e.*, Compound 127 of Table 7 - now renumber as Table 5) in a myocardial infarction animal model. In short, ¶7 identifies the surgical preparation involved, ¶8 summarizes the various procedures employed, and ¶9 addresses assessment of the area at risk and infarct site. The results of this animal testing is presented in

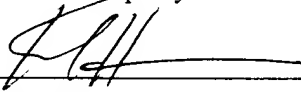
¶10, which found a 30% reduction in the infarct site by dosing with Compound 127 at 12 mg/Kg for 24 hours.

Accordingly, for the reasons set forth above, Applicants respectfully submit that pending claims 24-153 satisfy the first paragraph enablement requirement of §112, and request that this ground of rejection be withdrawn.

In addition, and assuming the Examiner finds new claims 24-153 allowable, Applicants respectfully request that withdrawn method claims 15-23 be rejoined for further prosecution. To that end, Applicants request that these method claims be renumbered as new claims 154-162, respectively, and amended to depend from pharmaceutical composition claim 153 (as opposed to canceled claim 14).

A good faith effort has been made to place this application in condition for allowance. However, should any further matter require attention, the Examiner is respectfully requested to contact the undersigned at (206) 622-4900 to address the same.

Respectfully submitted,  
Donald S. Karanewsky et al.  
Seed Intellectual Property Law Group PLLC

  
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Karl R. Hermanns  
Registration No. 33,507

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Enclosures:

Terminal Disclaimers re: U.S. Patent Nos. 6,197,750 and 6,544,951  
Sequence Listing (electronic and paper copies)  
Copy of U.S. Patent Nos. 6,197,750 and 6,544,951  
Declaration of Alfred P. Spada, Ph.D.

701 Fifth Avenue, Suite 6300  
Seattle, Washington 98104-7092  
Phone: (206) 622-4900  
Fax: (206) 682-6031

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